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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Erik Peter Bleuel

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EXAMINER

MA, JAMESON Q

ART UNIT

PAPER NUMBER

4153

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,489	Applicant(s) BLEUEL ET AL.	
	Examiner JAMESON Q. MA	Art Unit 4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060213</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 21-22 are objected to because of the following informalities: they are claims to a processor that are dependent to a method claim. Appropriate correction is required.
2. Claim 23 is objected to because of the following informalities: it is a claim to the use of a processor that is dependent to a method claim. Appropriate correction is required.

Claim Interpretation

3. For examination purposes, claims 21-23 have been treated as dependent to independent claim 20.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13, 15, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 13, 15, 18, and 19, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Visinoni et al. (EP 0 822 403) in view of Fanta et al. (US 2001/0006698).

Regarding claims 13-14, Visinoni discloses a method for processing a biological sample for histological analysis comprising the steps of:

- contacting the sample with dehydrating agent (see C1/L25-31).
- removing the dehydrating agent (see C1/L32-35).
- Replacing a clearing fluid by infiltrating an embedding medium, preferably paraffin, at a pressure of at least 1 bar (see C1/L41-46, C5/L9, and C5/L26-28).

Additionally, Visinoni discloses that the dehydrating agent can be ethanol (see C3/L15-16).

Visinoni does not explicitly disclose the method comprising the step of removing the dehydrating agent with a composition comprising a supercritical or a near supercritical fluid at a temperature in the range of 0.7 to 1.4 times its critical temperature and at a pressure in the range of 0.3 to 7 times its critical pressure. Visinoni also does not disclose said supercritical fluid or near supercritical fluid as carbon dioxide.

Fanta discloses a method for removing ethanol from a solid residue by contacting the sample with supercritical carbon dioxide (see [0057]).

Visinoni and Fanta are analogous because both references are concerned with removing ethanol from a solid sample.

It would have been obvious to substitute for the clearing agents in the method of Visinoni, supercritical carbon dioxide as taught by Fanta, because doing so would amount to nothing more than the simple substitution of one known method for removing ethanol from a solid sample for another to obtain predictable results. Since Fanta discloses the use of supercritical carbon dioxide, it is further inherent that fluid would satisfy being at a temperature in the range of 0.7 to 1.4 times its critical temperature and at a pressure in the range of 0.3 to 7 times its critical pressure.

Regarding claim 15, modified Visinoni discloses all of the claim limitations as set forth above. Additionally, Visinoni discloses the method:

- wherein said biological sample is a fresh, frozen or fixed tissue sample, preferably a fresh, non-fixed sample (see C2/L28: the sample is fixed).

Regarding claims 17-18, modified Visinoni discloses all of the claim limitations as set forth above. Additionally, modified Visinoni discloses the method:

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- wherein said sample is dehydrated, defatted and/or decalcified prior to impregnation by using a composition comprising a supercritical fluid (see Visinoni C2/L28-38: dehydration and clearing are performed before impregnation, and the clearing step of modified Visinoni includes use of supercritical carbon dioxide).
- wherein said composition additionally comprises a dehydrating agent, preferably an alcohol (see Visinoni C3/L15-19).

Regarding claim 16, modified Visinoni discloses all of the claim limitations as set forth above.

Visinoni additionally discloses the processing is to be performed on organic tissue (see abstract). Visinoni discloses that specific types of tissues to be tested are those largely composed of keratin, dense collagen, closely packed smooth muscle fibres, colloid areas of haemorrhage, thrombi or yolk and fatty tissues (see C5/L35-45).

Visinoni does not explicitly disclose the method wherein said biological sample comprises an organ or a part thereof.

It would have been obvious to one of ordinary skill at the time of invention to use an organ as the source of tissue in the method of modified Visinoni because doing so would amount to nothing more than choosing from a finite number of identified and predictable solutions for sources of tissue largely composed of keratin, dense collagen, closely packed smooth muscle fibres, colloid areas of haemorrhage, thrombi or yolk and fatty tissues, with a reasonable expectation of success.

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Visinoni et al. (EP 0 822 403) in view of Fanta et al. (US 2001/0006698), as applied to claims 13-18 above, in

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further view of Frayssinet et al. (Histological integration of allogenic cancellous bone tissues treated by supercritical CO₂ implanted in sheep bones), and in further view of Mahwhinney et al. (Control of rapid nitric acid decalcification).

Regarding claim 19, modified Visinoni discloses all of the claim limitations as set forth above. Additionally, Visinoni teaches the method wherein fatty tissues are processed (see C5/L35-45).

Frayssinet discloses that bone is a fatty tissue (see P2248/C1/L1).

Modified Visinoni and Frayssinet are analogous because both references are directed to fatty tissues.

It would have been obvious to one of ordinary skill at the time of invention to use bone as a source of fatty tissue as taught by Frayssinet in the method of modified Visinoni, because doing so would amount to nothing more than choosing from a finite number of identified, predictable solutions for fatty tissue sources, with a reasonable expectation of success.

Modified Visinoni does not explicitly disclose the method wherein said composition additionally comprises a decalcifying agent, preferably an acid.

Mawhinney teaches that decalcification is commonly employed in most histopathology laboratories for the microscopical examination of bone and other calcified tissues in order to improve cytological detail (see P1409/C1/L1-7). Mawhinney also discloses the use of nitric acid as a decalcifying agent (see P1409/C2/L7-12)

Modified Visinoni and Mawhinney are analogous because both references are directed to processing bone samples for histological analysis.

It would have been obvious to one of ordinary skill at the time of invention to use in the method of modified Visinoni, nitric acid as a decalcifying agent as taught by Mawhinney, in order to provide improved cytological detail in bone samples prepared for microscopical examination.

11. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Visinoni et al. (EP 0 822 403) in view of Fanta et al. (US 2001/0006698), as applied to claims 13-18 above, in further view of Frayssinet et al. (Histological integration of allogenic cancellous bone tissues treated by supercritical CO₂ implanted in sheep bones).

Regarding claims 20-23, Visinoni discloses a processor for preparing at least one sample for histological analysis comprising at least one process reactor (see C6/L8-9: the dome is viewed as a reactor) for the at least one sample, at least one supplying means for adding the embedding medium to the reactor through conduit (see C6/L12-13 and Fig. 2: paraffin, the embedding medium, is transported into the dome), and further comprising pressurizing and or heating means for bringing a substance at the required pressure and or temperature (see C6/L8: microwave).

Modified Visinoni further teaches that supercritical carbon dioxide can be applied as a clearing agent of ethanol (see Visinoni C3/L15-16 and Fanta [0057]).

Modified Visinoni does not explicitly disclose the processor comprising supplying means for supplying to the reactor at least one substance of which at least one is in supercritical phase or near supercritical phase. Further, modified Visinoni does not teach the processor further comprising:

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- separating means for separating substances from a mixture of substances leaving the reactor.
- recycling means for recycling substances discharged from the reactor.

Frayssinet teaches means for supplying a supercritical fluid (see P2248/C1/L41-44: metallic membrane pump). Frayssinet also teaches separating means and recycling means for recycling previously used carbon dioxide (see P2248/C1/L46-50).

Modified Visinoni and Frayssinet are analogous because both references are directed to treating solids with supercritical carbon dioxide.

It would have been obvious to one of ordinary skill at the time of invention to incorporate the metallic membrane pump as taught by Frayssinet into the processor disclosed by modified Visinoni, because doing so would amount to nothing more than choosing from a finite number of identified, predictable solutions of supplying supercritical carbon dioxide to a chamber with a reasonable expectation of success. It would further have been obvious to incorporate the separating and recycling means as taught by Frayssinet into the processor of modified Visinoni, in order to reduce the amount of carbon dioxide required by the method.

Regarding claim 23, Modified Visinoni discloses all of the claim limitations as set forth above.

Visinoni further teaches the use of the processor as disclosed above for processing a biological sample (see abstract: organic tissues are biological samples).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-R 7:30 AM - 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on (571)272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1797
AU 4153 TA

JM
November 17, 2008